

### **REMARKS**

Claims 1, 3-6 and 8-47 are pending in the present application. However, claims 24-45 have been withdrawn from consideration. Accordingly, claims 1, 3-6, 8-23, 46 and 47 are being considered for further consideration on the merits. By way of this Amendment, claims 3 and 13 have been amended to expedite allowance.

#### **Objection to Claim 3**

Applicants have amended claim 3 to correctly depend on claim 1. Applicants thank the Examiner for noting this informality.

#### **Rejection of Claim 47 under 35 USC §112**

In response to the rejection of claim 47 under 35 USC §112, Applicants have amended claim 13 to recite "a deployment catheter" as part of the claimed invention. As a result, claim 47 now further limits the claimed invention.

#### **Rejection of Claims 1, 3, 5, 6, 8, 9, 11 and 12 under 35 USC §103(a)**

Claims 1, 3, 5, 6, 8, 9, 11 and 12 are rejected under 35 USC §103(a) as being unpatentable over Vidlund et al. (USPAP 2003/0130731) in view of Adams et al. (USPAP 2003/0083538). The Examiner asserts that Vidlund et al. discloses a medical device for remodeling a mitral valve annulus adjacent to the coronary sinus with all the elements of claim 1. However, the Examiner concedes that Vidlund et al. is silent to the central segment being concave in a second direction. Adams et al. teaches a device having a "w" configuration implanted into the coronary sinus, wherein a force is applied to a discrete portion of the atrial wall of the coronary sinus in order to reshape the mitral valve annulus for treating dilated cardiomyopathy. The Examiner then asserts that it would have been obvious to one of ordinary skill in the art to look to the teachings of Adams et al. to modify the device of Vidlund et al. such that the final shape of the device is of a "w." The Examiner further asserts that, because the central segment will be concave in a direction opposite to the concave direction shown in Figure 4i in the remodeling configuration, the forming element (90) will extend outside the body

(110h) by being exposed between the wedge-shaped segments (95) that make up the body along the central segment.

Applicants respectfully note that the cited references fail to disclose or suggest anything about a medical apparatus having a forming element for manipulating an elongate body into a "w" configuration. Furthermore, neither of the cited references discloses a forming element that extends outside the body along the central segment. In the Office Action, the Examiner asserted that, due to the shape of the device, "the forming element (90) will extend outside the body (110h) by being exposed between the wedge-shaped segments (95) that make up the body along the central segment." Applicants disagree with the Examiner's assertion. The fact that the forming element is exposed between the wedge-shaped segments should not be construed to mean that the forming element extends outside the body along the central segment. To use an analogy, the fact that a tiger can be seen through the bars of a cage does not mean that the tiger is outside the cage.

Vidlund et al. (as shown in Figures 4h and 4i) merely teaches a frame member (110h) in combination with an actuation mechanism (90). The actuation mechanism is configured to be pulled proximally for causing the frame member to change its shape for creating a single continuous curve, as shown in Figure 4i. Vidlund et al. fail to contemplate or suggest how an actuation mechanism may be used to manipulate an elongate body into a "w" configuration. Adams et al. (as shown in Figure 3) teaches a mitral valve device (50) formed from a shape memory material. The mitral valve device includes a pair of outwardly curved end portions (52, 54) that substantially continuously engage the pericardial (outer) wall (13) of the coronary sinus. The device also includes an inwardly curved portion (56) for applying a force to a localized discrete portion of the atrial (inner) wall of the coronary sinus. Adams et al. provides no teaching or suggestion regarding how a forming element may be combined with the elongate body of Vidlund et al. to create an implant that is adjustable from a flexible configuration to a "w" configuration. The mere fact that Vidlund et al. disclose a "forming element" and Adams et al. disclose a "w-shape body" does not mean that it would have been obvious at the time of the invention to modify the device of Vidlund et al. with the teachings of Adams et al. to construct

Applicants' claimed invention. A medical device having a forming element for manipulating an elongate body into a "w" shape is not disclosed anywhere in either reference.

Still further, in the "Response to the Arguments," the Examiner asserts that paragraph [0124] of Vidlund et al. "clearly indicates that the final shape of the frame member (110h) does not have to have a single continuous curve." Paragraph [0124] discloses that the shape of the frame member 110h may reduce or enlarge a radius of curvature of the valve annulus, or a combination of both. This statement refers to the fact that the valve annulus has an irregular shape and therefore the device taught by Vidlund et al. may cause the radius of curvature of the valve annulus to increase in one particular area, while decreasing in another area. Nothing in paragraph [0124] discloses or suggests that the shape of the device may have a varying curvature.

For at least the reasons discussed above, the combination of Vidlund et al. and Adams et al. cannot support a rejection of independent claim 1 under 35 U.S.C. §103(a). Accordingly, Applicants respectfully request that the Examiner withdraw the rejections of claims 1, 3, 5, 6, 8, 9, 11 and 12 under 35 U.S.C. §103(a).

**Rejection of Claims 4 and 10 under 35 USC 103(a)**

Claims 4 and 10 are rejected under 35 USC 103(a) as being unpatentable over Vidlund et al. and Adams et al. as applied to claims 1 and 8 above, and further in view of Alferness et al. (USPAP 2003/0105520). As discussed above, independent claim 1 is distinguishable over the cited combination of references. Accordingly, dependent claims 4 and 10 are also distinguishable over the cited references. Therefore, Applicants respectfully request that the Examiner withdraw the rejections of claims 4 and 10 under 35 U.S.C. §103(a).

**Rejection of Claims 13-23, 46 and 47 under 35 USC 103(a)**

Claims 13-23, 46 and 47 are rejected under 35 USC 103(a) as being unpatentable over Vidlund et al. in view of Adams et al. and Wester, Jr. (U.S. Patent No. 6,123,699) and Alferness et al. (USPAP 2002/0169504). The Examiner asserts that Vidlund et al. discloses a medical device for remodeling a mitral valve annulus adjacent to the coronary sinus with all the elements

of claim 13. However, the Examiner concedes that Vidlund et al. is silent to manipulation of the forming element deflecting the central section laterally with respect to at least a portion of the proximal and distal sections. The Examiner then asserts that it would have been obvious to one of ordinary skill in the art to look to the teachings of Adams et al. to modify the device of Vidlund et al. such that the final shape of the device includes a central segment that is laterally deflected. The Examiner then asserts that it would have been obvious to one of ordinary skill in the art to look to the teachings of Webster, Jr. to modify the implant of Vidlund et al. by having the forming element (90) attached to the central segment in order for the forming element to provide that section with a curvature.

The Examiner also concedes that Vidlund et al. is silent to a detachable coupling on the body for removably attaching the body to a deployment catheter, as further required by claim 13. The Examiner then asserts that Alferness et al. teaches the detachable coupling and that it would have been obvious to one of ordinary skill in the art to look to the teachings of Alferness et al. to modify the implant of Vidlund et al. to provide the claimed invention.

Applicants' independent claim 13 recites an improved implant device for positioning within a patient. The implant comprises an elongate flexible body having a proximal section, a central section and a distal section; a forming element extending through at least the proximal and distal sections of the body; and a detachable coupling on the body for removably attaching the body to a deployment catheter. The unique combination of components is assembled such that manipulation of the forming element causes the central section to deflect laterally with respect to at least a portion of the proximal and distal sections. The cited combination of references neither teaches nor suggests the structure recited by Applicant's independent claim 13.

A *prima facie* rejection for obviousness requires: (1) a disclosure or suggestion of every element of the claim in the cited reference or references; (2) a suggestion or motivation to modify or combine the references; and (3) a reasonable expectation of success. The suggestion to combine and the reasonable expectation of success must be found in the prior art or known to one skilled in the art. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The Examiner has not shown any suggestion or motivation to modify or combine the cited

references. Vidlund et al. teach a deflectable body which simply curves in one direction. Adams et al. teaches a mitral valve device that uses a friction fit or is formed from a shape memory material. Webster, Jr. merely teaches a steerable catheter. None of the cited references teaches or suggests a device wherein a forming element can be manipulated to deflect a central section laterally with respect to the proximal and distal sections to selectively apply a compressive force along a region of tissue for treating a mitral valve.

The Federal Circuit has further stated that it is impermissible simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps. Interconnect Planning Corporation v. Feil, 774 F.2d 1132, 1143 (Fed. Cir. 1985). The references themselves must provide some teaching whereby the applicant's combination would have been obvious. In re Gorman, 933 F.2d 982 (Fed. Cir. 1991). In the present application, Applicants submit that the attempted combination of references is based on impermissible hindsight reconstruction and the references do not provide any teaching that would have rendered Applicants' invention obvious.

In contrast to the structures disclosed in the cited references, the inventors of the present application have invented an improved device that has not been heretofore contemplated. Accordingly, Applicants respectfully request that the Examiner withdraw the rejections of claims 13-23, 46 and 47 under 35 U.S.C. §103(a)

#### **Fees Due to File This Amendment**

Prior to the pending Office Action, a fee was paid for the original 45 claims, with 5 of them being independent claims. The aforementioned claim additions and cancellations have not resulted in more than the original number of claims, and thus no claim fees are believed to be due to file this amendment.

NOV. 1. 2005 6:41PM EDWARDS LEGAL DEPT. 949-250-6885  
Application Serial No.: 10/034,655  
Amdt. dated November 1, 2005  
Reply to Office Action of July 1, 2005

NO. 2997 P. 12/12

**Petition for Extension of Time to Respond**

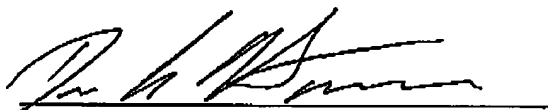
Pursuant to 37 C.F.R. 1.136(a), Applicants hereby request an extension of time for **One Month** to respond to the above-referenced Office Action. The Commissioner is hereby authorized to charge the required fee of \$120.00 to Deposit Account No. 50-1225 (Docket No. PVI-5813CIP2CIP1CIP1).

**Conclusion**

In light of the foregoing amendments to the claims and the above remarks, Applicants believe that this application is now in condition for allowance. Should the Examiner have any remaining questions, the Examiner is encouraged to contact the attorney of record at the telephone number shown below.

Respectfully submitted,

Date: November 1, 2005

  
David L. Hauser  
Registration No. 42,643  
EDWARDS LIFESCIENCES LLC  
One Edwards Way  
Irvine, California 92614  
Telephone: (949) 250-6878  
Facsimile: (949) 250-6850  
Customer No.: 30452